

Thealoz® Duo

This product is a medical device.
Please read the instructions
before use.
Keep this leaflet. You may need
to read it again.

INDICATIONS

THEALOZ DUO is indicated to protect, hydrate and lubricate the surface of your eyes, for treatment of moderate to severe dry eye syndrome.
For ocular use only.

SUITABLE FOR

- Adults,
- Children: Parents or carers should administer the product,
- Pregnant or breastfeeding women based on current knowledge,
- Wearers of any type of contact lenses.

CONTRAINDICATIONS

Do not inject and do not swallow.
Do not use THEALOZ DUO if you are allergic to any of its ingredients (see Device description).

DEVICE DESCRIPTION

THEALOZ DUO is a solution containing trehalose (3%), sodium hyaluronate (0.15%), sodium chloride, trometamol, hydrochloric acid and water for injections. THEALOZ DUO is a sterile, phosphate-free, hypotonic and pH neutral solution.

The solution is supplied in the patented ABAK® multi-dose bottle. This innovative design delivers eye drops through a 0.2 µm filter, preventing any bacterial contamination of the solution and avoiding the use of any chemical preservatives. This means THEALOZ DUO is gentle for eyes because it is preservative-free. Avoiding chemical preservatives is beneficial for the eye's surface long term and eliminates reactions amongst people who are sensitive to preservatives.

BENEFIT, PERFORMANCE AND MECHANISM OF ACTION

THEALOZ DUO is recommended if you have discomfort, stinging, foreign body sensations or irritation of your eyes due to moderate or severe ocular dryness. These symptoms can be caused by factors such as wind, smoke, pollution, dust, sunny or cold conditions, dry heat, air conditioning, plane journeys, long hours working in front of a computer screen or digital device and also by eye surgery such as refractive and cataract surgery.

THEALOZ DUO provides immediate comfort that lasts all day long, to relieve the symptoms of dry eyes as described above.

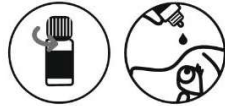
THEALOZ DUO is compatible with the delicate surface of your eyes, and can also be used by people wearing any type of contact lenses.

The main ingredients of THEALOZ DUO are trehalose and sodium hyaluronate: this unique combination of trehalose and sodium hyaluronate in THEALOZ DUO provides long-lasting protection, hydration and lubrication of the eye surface. Trehalose is a natural substance found in many plants and animals, which need to survive in extreme conditions of temperature and dryness. It provides protective and hydrating properties. Sodium hyaluronate, naturally found in the human eye, holds water to hydrate and lubricate the surface of the eye. It keeps the solution on the eye surface, giving long lasting relief and cutting down the healing time of the ocular surface.

GENERAL RECOMMENDATIONS FOR USE

Apply 1 drop to each eye, from 4 to 6 times daily.

THEALOZ DUO is easy to use. Do not use any tool to open the bottle. Wash hands thoroughly before use.
When you first use THEALOZ DUO, you will find the first drop takes longer to come out due to the unique filtration system in the bottle (see Device description). Apply one drop in the pocket of the eyelid, while gently pulling the lower lid down and looking up. Close the eye gently after application.
Replace the bottle cap after use.



CAUTIONS FOR USE

Multi-dose bottle, for use by one person only.

Do not share bottles between different people to prevent cross contamination.

Check the packaging and tamper-proof ring are intact before using this product for the first time. To avoid contamination, do not touch the tip of the bottle with anything. You must contact a healthcare professional if your symptoms get worse or do not improve.

WARNINGS

Keep out of the sight and reach of children.
After use, do not drive or use machines if your vision is blurred: wait for a few minutes until your vision clears.
Wait at least 10 minutes between using two different eye products. Never dilute THEALOZ DUO or mix it with other solutions.
Once opened, if you expose the bottle to low atmospheric pressure (such as on an airplane), the bottle may leak.

SIDE EFFECTS

The following side effects have been reported: rare possibility of mild eye irritation and ocular redness.
In such cases, contact lens wearers should remove their contact lenses.

When you use eye drops, you might experience disturbing symptoms such as burning sensation, stinging sensation, foreign body sensation in the eye and blurred vision for a short time.

If you notice any side effects or unusual sensations after using this product, please contact a healthcare professional and report the information to the local distributor, to the manufacturer or to your local Health Authority (see contacts at the end of the instructions for use).

STORAGE AND DISPOSAL CONDITIONS

Store between 8 °C and 30 °C. Do not expose your product to direct sunlight or humidity. Do not use after the expiry date, which is marked on the bottle and on the outer box.
The expiry date refers to the last day of that month as long as the packaging is intact and it has been stored correctly.
The product can be used until 6 months after first opening. After this time, discard any leftover product responsibly.

Dispose of the product responsibly and in accordance with local guidance (the bottle should be disposed of as household waste, the outer carton and the leaflet are recyclable).

Date of issue and version of the instructions for use:
Ver.7 11/2021

Manufacturer:

Laboratoires Théa
12 rue Louis Blériot
63017 Clermont-Ferrand
Cedex 2 France
www.laboratoires-thea.com
« Contact us » section

GB

Distributor:

THEA Pharmaceuticals Ltd,
MED IC5, Innovation Way, Keele
University Science and Innovation
Park, Keele, Newcastle Under
Lyme, Staffordshire, ST5 5NT
www.thea-pharmaceuticals.co.uk
Tel.: 0345 521 1290

Health authority:

Medicines and Healthcare products
Regulatory Agency, 10 South
Colonnade, London, E14 4PU
Tel.: 020 3080 6000

IE

Distributor:

Thea Pharma Ltd, Golden Mile
Industrial Park, Breafoy Road,
Castlebar, Co Mayo F23D299
Tel.: 0 94 92 50290

Health authority:

Health Products Regulatory
Authority, Kevin O'Malley House,
Earlsfort Centre, Earlsfort Terrace,
Dublin 2, D02 XP77
Tel.: 1 676 4971

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MEANING OF THE PICTOGRAMS ON THE PACKAGING

	Manufacturer
	Medical Device
	Batch number
	Consult instruction for use
	Date of manufacture
	Single patient – Multiple use
	Use-by date
	Do not use if package is damaged
	Temperature limits
	Caution
	Sterilized using aseptic processing techniques